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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

DEPOMED, INC.,

Plaintiff,

v.

ACTAVIS ELIZABETH LLC et al.,

Defendant.

No: 3:12-CV-01358 JAP (TJB)

MEMORANDUM OF LAW IN SUPPORT OF DEPOMED INC.'S MOTION IN LIMINE NO. 1 TO STRIKE PARAGRAPHS 67-74, 92-97, 106 AND 125 FROM DR. FRIEND'S REBUTTAL EXPERT REPORT AND TO EXCLUDE ANY TESTIMONY THEREOF

Honorable Joel A. Pisano

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I. INTRODUCTION

Plaintiff Depomed, Inc. ("Depomed") moves *in limine* to strike those portions of the expert report and deposition testimony of Dr. David Friend going to Actavis's[1] novel affirmative noninfringement arguments with regard to claim terms "release by diffusion" and "remains substantially intact." These affirmative theories were unknown to Depomed until it received Actavis Dr. Friend's opinion during the rebuttal round of expert reports. Such tardy disclosure came despite requirements for Actavis to notify Depomed of its noninfringement theories in its Local Patent Rule 3.6 Non-Infringement Contentions and in responses to Depomed's Requests for Admission ("RFA"). As such, the Court should apply the mandatory exclusionary sanction of Federal Rule of Civil Procedure 37(c)(1) ("Rule 37(c)(1)") to strike these novel theories or exercise its discretionary authority to order exclusionary issue sanctions under Federal Rule of Civil Procedure 16(f) ("Rule 16(f)") and under Federal Rule of Evidence 403 ("Rule 403").

II. DR. FRIEND'S REBUTTAL REPORT CONTAINS PREVIOUSLY UNDISCLOSED THEORIES OF NON-INFRINGEMENT

Actavis served its initial Non-Infringement Contentions on August 12, 2012, and its Non-Infringement Contentions covering the '332 Patent on December 3, 2012, as required by the Scheduling Orders of this Court. In those contentions,

[1] Defendants Actavis Elizabeth LLC and Actavis LLC (collectively "Actavis").

Actavis was to "specifically identify for each claim which claim limitation(s) is/(are) literally absent from each opposing party's infringing [ANDA.]" *See* Local P.R. 3.6(e). Actavis ***conceded infringement*** of "release by diffusion"[2] by omitting from the narratives it provided in its Non-Infringement Contentions ***any*** theories of non-infringement. (Ex. 1[3] at 7, 8, 12, 13, 15, 19; Ex. 11 at 5-8.) And in its accompanying charts, Actavis wrote nothing about any limitations reciting "release by diffusion," (Ex. 1 at 8, 13, 16, 17, 19; Ex. 11 at 9), even though the Local Patent Rules require defendants to identify in their charts where each limitation is literally absent. Local. P.R. 3.6(e). Actavis never moved to amend its Non-Infringement Contentions.

[2] The property of a recited dosage form releasing drug "by diffusion" appears in some form in claim 1 of the '280 Patent ("that releases said drug into gastric fluid by the dissolution and diffusion of said drug out of said matrix by said gastric fluid"), claims 17 and 33 of asserted U.S. Patent No. 7,438,927 ("the '927 Patent") ("and wherein upon contact with water, gabapentin is released by diffusion from the dosage form"), claim 1 of asserted U.S. Patent No. 7,731,989 ("the '989 Patent") (same), and claim 6 of asserted U.S. Patent No. 8,252,332 ("the '332 Patent") ("wherein gabapentin is released from the polymer matrix by diffusion"). Depomed moves *in limine* with regard to Dr. Friend's opinion and testimony touching on each of these "by diffusion" elements.

[3] All citations to "Ex. _" are to the exhibits attached to the Declaration of Daniel K. Greene In Support of Depomed, Inc.'s Motion *In Limine* Nos. 1-6 filed concurrently herewith.

As for "remains substantially intact,"[4] Actavis identified certain asserted claim limitations it believed were absent in its accused products, but did not include claim limitations reciting "remains substantially intact" among them. Rather, Actavis merely asserted that Depomed could not prove infringement of this element. (Ex. 1 at 7 (omitting non-infringement theory from narrative response), 8 (same), 12 (same), 8 (indicating in infringement charts that it is leaving Depomed to its proofs), 13 (same).)

On June 6, 2013, Depomed served its first set of RFAs on Actavis in order to, among other things, simplify the issues for trial by obtaining admissions that Actavis infringes certain of the asserted claims. (Ex. 2.) In many cases Depomed sought admissions on claim elements that Actavis had not disputed in its Non-Infringement Contentions.

Actavis responded to these RFAs on July 22, 2013, after Depomed extended the time for Actavis to respond with the understanding that Actavis would provide "considered and complete response[s]." (Ex. 3 (email from B. Sadasivan to J. Murata (July 1, 2013 (2:42 PM).) Actavis's substantive response to RFA No. 32 is representative. Therein Actavis admits that, after a "reasonable investigation,"

[4] This term appears in Claim 1 of asserted U.S. Patent No. 6,635,280 ("the '280 Patent") in full as: "and that remains substantially intact until substantially all of said drug is released."

Actavis was unable to determine whether its accused [redacted]

[redacted]

REQUEST FOR ADMISSION NO. 32:

Admit that, upon contact with water, Actavis's proposed 300 mg oral dosage form, as currently formulated for approval under ACTAVIS'S ANDA, releases gabapentin by diffusion from the dosage form.

[SUBSTANTIVE] RESPONSE TO REQUEST FOR ADMISSION NO. 32:

[redacted] After a reasonable investigation, Actavis has insufficient information to admit or deny the remainder of this Request and therefore leaves Depomed to its proofs.

(Ex. 4; *see also id.* at RFA Nos. 33 (admitting after "reasonable investigation" it could not determine whether [redacted]), 66 (same), 92 (same), 156 (same), 157 (same), 195 (same), 220 (same), 103 (neither denying nor admitting as to "remains substantially intact" and "leav[ing] Depomed to its proofs"), 231 (same).) Actavis never moved to amend its contentions and did not serve amended responses to

Depomed's RFAs.[5] Actavis has, however, promised the Court in another context in this case that its own use of RFAs sought "to 'crystallize [the] theories of the case.'" (ECF No. 213 at 1 (quoting *TFH Publ'n, Inc. v. Doskocil Mfg., Co., Inc.*, 705 F. Supp. 2d 361, 365-66 (D.N.J. 2010) (citing *Atmel Corp. v. Info. Storage Devices, Inc.*, No. 95–1987 (FMS), 1998 WL 775115, at *2 (N.D. Cal. Nov. 5, 1998)) ("The Local Patent Rules are 'designed to require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed.'").)

Despite this lack of disclosure required by the Local Patent Rules and lack of forthright representation in its responses to Depomed's RFAs, on March 19, 2014, Actavis provided affirmative noninfringement theories for the first time through Dr. Friend's rebuttal expert report. Regarding "release by diffusion," Dr. Friend opined that a person of ordinary skill would distinguish between diffusion and erosion or some other mechanism, [redacted]

[redacted]

[5] Notably, Actavis did not amend its contentions or responses to RFAs relevant to "remains substantially intact" even though it knew at least by January 2013 that the Court would adopt most, if not all, of Depomed's proposed construction for this term. On January 22, 2013, Actavis filed its opening claim construction brief where it proposed a construction for "remains substantially intact" that was in large part identical to Depomed's construction the Court adopted but for two small differences. (ECF No. 139 at 7.) These circumstances beg the question: why did Actavis not figure out whether its accused product remains substantially intact in view of the similarities of the parties' proposed constructions?

[redacted] (Ex. 5 ¶¶ 92-97, 106, 125.) As for "remains substantially intact," Dr. Friend opined that the Court's construction of this term[6] does not apply to Actavis's accused products [redacted] (*Id.* ¶¶ 67-74.) Dr. Friend attempted at deposition to provide further evidence of these untimely, affirmative non-infringement arguments. (Ex. 6 at 163:20-166:14 (release by diffusion), 175:14-176:11 (same), 44:21-45:15 (remains substantially intact), 142:1-148:19 (same).)

III. THE COURT SHOULD STRIKE ACTAVIS'S NOVEL THEORIES AND EXCLUDE EXPERT TESTIMONY THERETO

The Court should grant Motion *In Limine* No. 1 and strike from Dr. Friend's rebuttal expert report the testimony in paragraphs 67 through 74 ("remains substantially intact"), and paragraphs 92 through 97, 106, and 125 ("release by diffusion"). The Court should also exclude any of Actavis's experts from testifying as to these theories at trial. This relief is proper for three reasons: (A) the mandatory exclusionary sanction provided in Rule 37(c)(1) applies to these opinions and testimony, as do the discretionary exclusionary sanctions available under (B) Rules 16(f), and (C) Rule 403.

[6] "[A] polymeric matrix in which the polymer portion substantially retains its size and shape without deterioration due to becoming solubilized in the gastric fluid or due to breakage into fragments or small particle." (ECF No. 251 at 18-19.)

A. THE MANDATORY EXCLUSIONARY SANCTION OF RULE 37(C)(1) APPLIES TO ACTAVIS'S VIOLATION OF THE SCHEDULING ORDER

There is no question that Actavis violated the Court's Scheduling Order when it belatedly identified novel non-infringement theories for the first time in Dr. Friend's rebuttal expert report served on March 19, 2014, while the Scheduling Order required that Actavis serve its applicable Non-Infringement Contentions more than one year ago on August 24, 2012 or December 3, 2012. (ECF Nos. 63, 103.)

The mandatory exclusionary sanction of Rule 37(c)(1) can apply to information withheld in violation of a Scheduling Order and first presented via expert testimony. *See, e.g.*, *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 719 (3d Cir. 1994); Fed. R. Civ. P. 37(c)(1). Exclusion of the withheld information is mandatory unless Actavis can show that its failure to obey the Scheduling Order is "substantially justified or harmless." *See* Fed. R. Civ. P. 37(c)(1). The rule also provides that the parties may move the Court to increase or decrease the severity of the sanctions, but the default sanction is exclusion. *See id*.

As the party violating the Scheduling Order, Actavis must carry the heavy burden of showing that its violation is "substantially justified or harmless" and mandatory exclusion is not warranted. *See Am. Stock Exchange LLC v. Mopex, Inc.*, 215 F.R.D. 87, 93 (S.D.N.Y. 2002) (stating burdens). Depomed is hard pressed to find any justification (much less ***substantial*** justification) for Actavis's

delay in articulating these non-infringement theories. ***First***, with the exception of the '332 Patent, each patent containing the "release by diffusion" and "remains substantially intact" terms was asserted in the original complaint filed by Depomed nearly a year-and-a-half ago. (ECF No. 1 ¶¶ 30, 32, 34, 35; n. 2, *supra*.) Shortly thereafter on September 28, 2012, Depomed amended its complaint to further allege infringement of the '332 Patent. (ECF No. 101 ¶¶ 194-200; n. 4, *supra*.)

Second, Depomed filed this lawsuit after receiving Actavis's Notification Letter in January 2012, before which Actavis presumably investigated the likelihood of infringement of the patents-in-suit. After the Court granted Depomed leave to amend its complaint to include the '332 Patent, Actavis responded with a similar Notification Letter stating reasons why, in its view, all claims of that patent were invalid and not infringed by the Actavis ANDA products.

Third, statements in Actavis's claim construction briefing reveal that Actavis knew at least by January 2013 that "remains substantially intact" would be construed to contain most, if not all, of Depomed's proposed construction that would later be adopted by the Court. (ECF No. 139 at 7; *see* ECF No. 251 at 18-19.)

Fourth, by August 2013, Actavis admitted to performing a "reasonable investigation" of whether its accused ANDA products infringed these claim elements. (Section II, *supra*.) Actavis nonetheless informed Depomed that it

"ha[d] insufficient information to admit or deny" infringement, and then never updated its response. The most logical inference is that gamesmanship is the reason for the delay.

Nor can Actavis show harmlessness. In this Circuit, harmlessness is determined by weighing the *Pennypack* factors. *See Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894, 904-05 (3d Cir. 1977), *overruled on other grounds*, *Goodman v. Lukens Steel*, 777 F.2d 133 (3d Cir. 1985). No one *Pennypack* factor is dispositive, and the Court should look to the overall balance of the factors when assessing harmlessness. The *Pennypack* factors are: (1) the importance of information withheld; (2) the prejudice or surprise to the party against whom the evidence is offered; (3) the likelihood of disruption of the trial; (4) the possibility of curing the prejudice; (5) the explanation for the failure to disclose; and (6) the presence of bad faith or willfulness in not disclosing the evidence. *Pennypack*, 559 F.2d at 904-05. All of the *Pennypack* factors weigh in Depomed's favor.

***Pennypack* factor (1)**. The withheld information provides Actavis with an additional, previously unasserted non-infringement theory. Actavis maintained that it will not infringe even before asserting these novel theories. Thus, these novel theories clearly are not critical to Actavis's case.

***Pennypack* factor (2).** The prejudice to Depomed, which is easy to identify, warrants significant discussion. Depomed assumed, incorrectly as it turns out, that Actavis would timely disclose complete and correct non-infringement theories as required by the Scheduling Order and the Local Patent Rules. (ECF No. 63.) Depomed and/or its experts unknowingly relied during fact discovery, claim construction, and expert discovery on Actavis's incomplete contentions and discovery responses. The case schedule presents Depomed with no opportunity to respond[7] to these novel theories before trial: fact and expert discovery have long been closed; the case is on the eve of trial; and trial cannot be moved because the end of the regulatory 30-month stay is fast approaching.

***Pennypack* factors (3) and (4).** Actavis introduced these theories for the first time in a rebuttal expert report served after the close of fact discovery and near the close of expert discovery. As such, Depomed has had no opportunity to vet these theories through fact discovery, and the Scheduling Order does not provide

[7] Depomed served the Second Expert Report of Dr. Harold Hopfenberg and of Dr. Robert Williams on April 4 and 8, 2014, respectively. These reports were offered under Fed. R. Civ. P. 26(a)(2)(D)(ii) in order to rebut the untimely opinion of Dr. Friend on "remains substantially intact" and "release by diffusion," as well as the previously undisclosed experimental results of Actavis expert Dr. Aeri Park on which Dr. Friend relies. The Court should strike paragraphs 67-74,92-97, 106, and 125 from Dr. Friend's expert report as well as any ancillary testimony thereto notwithstanding Depomed's service of the above-mentioned reports. However, should the Court nonetheless allow Dr. Friend's opinion to remain part of the record, then fairness dictates that the Court deny any motion by Actavis to strike the Second Expert Reports of Drs. Hopfenberg and Williams, as well as all further deposition testimony on the subject.

for reply expert reports (where Depomed could respond in the ordinary course). Because the 30-month stay preventing regulatory approval of the Actavis ANDA products is nearing an end on July 20, 2014, there will be no opportunity to cure the prejudice before trial (as discussed in detail below).

***Pennypack* factors (5) and (6).** Actavis has not — and in fact cannot — provide reasons to excuse its failures to comply with the Scheduling Order and Local Patent Rules.

In sum, the relief sought by Depomed in Motion No. 1 is proper and required under Rule 37(c)(1). *See Paoli*, 35 F.3d at 719. Indeed, district courts in this Circuit have invoked Rule 37(c)(1) to grant the relief Depomed requests in similar circumstances and in accordance with Pennypack. For example, in *Reckitt Benckiser Inc. v. Tris Pharma, Inc.*, the court affirmed the ruling that the *Pennypack* factors supported striking an expert report containing data and information not previously disclosed. C.A. 09-3125, 2011 WL 6722707, at *7-9 (D.N.J. Dec. 21, 2011).

B. THE MANDATORY EXCLUSIONARY SANCTION OF RULE 37(C)(1) APPLIES TO ACTAVIS'S VIOLATION OF ITS DUTY TO SUPPLEMENT INCOMPLETE RESPONSES TO DISCOVERY REQUESTS

As noted above, Actavis never served supplemental responses to Depomed's RFAs, even though it learned from Dr. Friend that its responses were incomplete because they did not incorporate Dr. Friend's novel theories. This conduct is also

sanctionable. Rule 37(c)(1) provides that failure to supplement responses to RFAs as required by 26(e) is subject to mandatory exclusion as described above. *See* Fed. R. Civ. P. 37(c)(1), 26(e)(1)(A). Moreover, Actavis has previously told the Court that RFA responses should not be subject to discovery deadlines because they are a "means to narrow the issues" ahead of trial. (ECF No. 213 at 8.) For the reasons just discussed, Actavis will not be able to show that its failure to supplement was either "substantially justified or harmless." (*See* Section III(A), *supra*.)

C. THE RELIEF SOUGHT BY DEPOMED IS ALSO PROPER UNDER RULE 16(F)

Rule 16(f) provides that sanctions are available when a party "fails to obey a scheduling or other pretrial order," including the Local Patent Rules. *See* Fed. R. Civ. P. 16(f)(1)(C); *Guimaraes v. NORS*, 366 Fed Appx. 51, 54 (11th Cir. 2010); *O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1363 (Fed. Cir. 2006). Rule 16(f) does not provide for automatic exclusion; however, Rule 16(f) permits the Court to order exclusionary issue sanctions. *See* Fed. R. Civ. P. 16(f)(1) (providing for sanctions available under Rule 37(b)(2)(A)(ii)-(vii), which include issue sanctions).

The relief Depomed requests is proper pursuant to Rule 16(f), because the Local Patent Rules were promulgated to prevent the very type of sandbagging Actavis has engaged in here. Parties are required to articulate their contentions

early so that "[b]y the time the parties are scheduled to exchange expert reports, they should be acutely aware of the other side's contentions and/or counter contentions." *Sanofi-Aventis v. Barr Labs., Inc.*, 598 F.Supp.2d 632, 637 (D.N.J. 2009); *see also O2 Micro*, 467 F.3d at 1359; *Merck Sharp & Dohme Corp. v. Sandoz, Inc.*, C.A. No. 12-3289, 2014 WL 997532, at *3 (D.N.J. Jan. 6, 2014); *King Pharms, Inc. v. Sandoz, Inc.*, Civ. No. 08-5974, 2010 WL 2015258, at *4 (D.N.J. May 20, 2010). These principles are doubly important in a Hatch-Waxman case. *Janssen Prods., L.P. v. Lupin Ltd.*, Case No. 10-5954, 2013 WL 3086378, at * 2 (D.N.J. June 18, 2013) ("Because this action arises under the Hatch-Waxman Act, it is even more imperative that the parties establish their contentions early" so that the parties and their experts can "fully explore[] and scrutinize[]" those contentions."); *Sanofi-Aventis*, 598 F.Supp.2d at 637 ("Local Patent Rule 3.6 requires ***ultra*** early disclosure of infringement and invalidity contentions for patent cases arising under the Hatch-Waxman Act.") (emphasis in original).

What's more, by belatedly disclosing these novel theories without showing the diligence and good cause required to amend its non-infringement contentions, Actavis has usurped the Court's authority to define the boundaries of this litigation. L. Pat. R. 3.7; *O2 Micro*, 467 F.3d at 1364 (moving party bears burden to demonstrate diligence and good cause on a motion to amend contentions). Indeed, "[i]t is for the Court to make the determination of whether a new theory is

consistent with an earlier contention or otherwise appropriate, not the party asserting it." *See Kilopass Tech. Inc. v. Sidense Corp.*, Case No. 10-2066, 2012 WL 3545286, at *8 (N.D. Cal. Aug. 16, 2012).

District courts with local patent rules frequently bar a party from asserting theories at trial that were not timely disclosed in contentions. For example, in *Fujitsu Ltd. v. Belkin Int'l, Inc.*, the court struck those portions of an expert's infringement report relying on third party products where the plaintiff had not previously disclosed their relevance in its infringement contentions, noting that the defendants would be "significantly prejudiced if [plaintiff] were allowed to proceed with its claims" based on the belatedly identified contentions. Case No. 10-cv-3972, 2012 WL 4497966, at *9-10 (N.D. Cal. Sept. 28, 2012). Other courts have similarly held. *See, e.g.*, *Kilopass*, 2012 WL 3545286 at *8; *Spectros Corp. v. Thermo Fisher Scientific*, Case No. 09-1996, 2012 WL 1965887, at *6 (N.D. Cal. May 31, 2012) (barring doctrine of equivalents theory for failure to amend infringement contentions); *Apple v. Samsung Elecs. Co., Ltd.*, Case No. 11-CV-1846, 2012 WL 3155574, at *6 (N.D. Cal. Aug. 2, 2012) (affirming striking by Magistrate Judge of portions of expert reports containing a "late disclosed non-infringement theory which Samsung disclosed after fact discovery," the late disclosure of which "impeded Apple's ability to test these contentions through fact discovery").

Exclusion is warranted here as well. Actavis — like the litigants in the above cases — has, through Dr. Friend's rebuttal expert report, unilaterally attempted to amend its contentions too late and without making the requisite showing of good cause.

D. THE RELIEF SOUGHT BY DEPOMED IS PROPER UNDER RULE 403

In Section III(A) above in analyzing *Pennypack* factor 2, Depomed explained the unfair prejudice that will result if the Court admits evidence supporting these untimely non-infringement theories. Exclusion is proper under Rule 403[8] in this circumstance because one-sided presentation of novel non-infringement theories will "cloud[] impartial scrutiny and reasoned evaluation of the facts, which inhibits the neutral application of principles of law to the facts as found." *See Goodman v. Pa. Tpk. Comm'n*, 293 F.3d 665, 670 (3d Cir. 2002) (defining prejudice under Rule 403); *see also Genentech, Inc. v. Amgen, Inc.*, 289 F.3d 761, 774 (Fed. Cir. 2002) (affirming district court's ruling precluding Genentech from asserting infringement

[8] The few decisions in which courts have stated that the unfair prejudice aspect of Rule 403 does not apply in bench trials can be distinguished on their facts. *See Gulf States Utils. Co. v. Ecodyne Corp.*, 635 F.2d 517, 519 (5th Cir. 1981); *I.B.E.W. Local Union 380 Pension Fund v. Buck Consultants*, C.A. No. 03-4932, 2008 WL 2265269, at *3 (E.D. Pa. June 3, 2008); *Hussey v. Chase Manhattan Bank*, C.A. No. 02-7099, 2005 WL 2203146, at *7 (E.D. Pa. July 29, 2005); *Schultz v. Butcher*, 24 F.3d 626, 631-32 (4th Cir. 1994). Whereas in this case Depomed has not had the opportunity to vet through fact discovery the evidence it seeks to exclude, in those cases the litigants had their opportunities to vet the evidence during fact discovery (as they would in the typical case) but objected simply because the evidence was bad for their cases.

under theory not previously contended and finding "unavailing" Genentech's argument that Amgen would not be prejudiced by failure to amend).

As such, and for reasons of unfair prejudice, the Court should strike paragraphs 67 through 74, 92 through 97, 106, and 125 from Dr. Friend's expert report setting forth his affirmative non-infringement opinions regarding "releases by diffusion" and "remains substantially intact," and should exclude any testimony thereto. *See* Fed. R. Evid. 403.

IV. CONCLUSION

For the foregoing reasons, Depomed respectfully requests that the Court grant Depomed's Motion *In Limine* No. 1 by striking from Dr. Friend's expert report the opinions contained in paragraphs 67 through 74, 92 through 97, 106 and 125 and excluding any Actavis expert from testifying thereof.

Dated: April 22, 2014

Respectfully submitted,

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